

# Clinica

Medtech Intelligence

Issue 1372 March 2011



## Perfect companions

Using genetic tests to tailor drug treatment to the patient

### INSIDE

Improving EU regulation of companion diagnostics

Off-label promotion and the US FDA

Interviews: Gen-Probe and Lab21

# Medtech Ventures

This month we profile BioMarker Strategies, which is developing a live solid tumour testing system to enable next-generation predictive tests for cancer; Alacris Theranostics, with its modelling system that acts as a “virtual patient” for doctors to determine the best cancer therapy; and Metamark Genetics, which is developing assays to help identify which patients have aggressive or indolent prostate cancer

## Hot pick of the month

### BIOMARKER STRATEGIES

**Specialty area(s):** Functional analysis of living tissue samples

**Based in:** Baltimore, Maryland, US

**Founded in:** 2006

**No. of employees:** 10

**Total investment received to date:**

Around \$9m in equity investment and grants

**Investors:** Private investors

With the pharma industry eschewing the blockbuster drug model in favour of targeted therapeutics, the demand for companion diagnostics which can help doctors determine which drug works best for each individual patient is growing.

To date, personalised medicine has made most impact in oncology. However, only a handful of companion diagnostic tests are available in the market, most of which are based on DNA/RNA mutation and gene expression analysis. This, says Scott Allocco, president of BioMarker Strategies, is because much of the research around molecular tests has been conducted, until now, on “static biomarkers” in dead, fixed tumour cell samples.

“Currently, the first thing you do when you take a biopsy from a patient is to kill the tumour cells,” says Mr Allocco. “These samples are placed in formaldehyde and embedded in wax, so they can be preserved for morphologic review for a very long time. But the process compromises the biological integrity of the sample.” As a result, important information about how the tumour functions is missing. This limits understanding of a tumour’s biology, and consequently impedes the advancement of effective cancer diagnostics and treatment.

To address this issue, BioMarker

Strategies is developing a system that will allow the ex vivo testing of live tumour cells, obtained from biopsies of solid tumours. Use of the system involves several steps. First, the sample is put through a processing device called SnapPath. Using automated fluidic technologies, the device is designed to break up the biopsy tissue sample into “aggregations of living tumour” and then remove non-tumour cell constituents from the sample. The sample is manipulated within the device to evoke a new class of ex vivo (phosphoprotein) biomarkers that did not exist in the unstimulated sample. Samples are then analysed off-platform to develop a functional signalling profile (FSP) of the patient’s tumour.

“It’s a tool to develop new indications for existing drugs, to co-develop new drugs and companion diagnostics and to better utilise currently approved drugs”

“We move portions of this live tissue sample into different test wells, where we can experiment on them with various growth factors to stimulate biological activity and activate some of the pathways in the cell, as well as exposing the living tumour cells to drug inhibitors,” explains Mr Allocco. The FSP obtained at the end of this process highlights the cancer cell’s complex signal transduction network, the pathways

via which a signal from outside the cell is communicated to the nucleus, resulting in a functional change within the cell.

“It is through this method that we are developing a series of ex vivo biomarker tests to predict patient response to both single agents and combinations of targeted cancer therapeutics. None of this can be done with a dead, fixed cell,” Mr Allocco tells *Clinica*.

Mr Allocco says that the firm could approach the market in several ways. Firstly, the FSP test could be used by BioMarker Strategies for drugs that have already been approved, but which have not been working as well as expected. “The drug may only be effective in 40% of patients but there are no biomarkers available to determine which 40% are going to benefit from that drug,” says Mr Allocco. “Another scenario is with drugs that are currently under development, where we can help to stratify the patient population who will best benefit.”

“We will also have the ability to better inform clinical decision-making for different classes of drugs,” he continues. “In the future, where there might be 10 different types of targeted drugs for advanced breast cancer patients, our approach could provide more clinically actionable information for oncologists to choose between multiple targeted drugs. So it’s a tool to develop new indications for existing drugs, to co-develop new drugs and companion diagnostics and to better utilise currently approved drugs.”

The firm has already initiated discussions with several companies “which are interested in the research application of the platform”, while it continues to

develop the technology for broader commercialisation.

In terms of regulatory approval, the company projects that the SnapPath tissue processing device will ultimately be regulated as a Class I device, and go through the 510(k) clearance process. The firm envisages that the device will be installed in hospitals around the country. "Live tissue biopsies will be processed in our machine to stabilise the sample for

shipment to our lab for the off-platform analysis of the ex-vivo biomarkers," says Mr Allocco. At some point in the future, the company hopes to integrate both components of its system – the live tissue processing and the FSP testing – into one "sample to result" SnapPath device. But for now, the firm is squarely focused on finishing development of SnapPath's sample processing technology so that it can be used for research purposes in biomarker-based

clinical trials later this year. Then, once it gets the 510(k) green light from the FDA, it plans to commercialise the platform more broadly for clinical uses.

*Scott Allocco, president.*

*Tel: +1 410 522 1008.*

*Email: [sallocco@biomarkerstrategies.com](mailto:sallocco@biomarkerstrategies.com)*

*BioMarker Strategies Inc. 855 N Wolfe*

*Street, Suite 623, Baltimore, MD 21205, US.*

*[www.biomarkerstrategies.com](http://www.biomarkerstrategies.com)*